

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 12394560/JEH/RBR | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
| International application No. PCT/AU2004/000018 | International filing date (<i>day/month/year</i>) 9 January 2004 | Priority date (<i>day/month/year</i>) 9 January 2003 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. 7 A 61K 31/215; A 61 P 31/22 | | |
| Applicant PENAM INVESTMENTS PTY LTD et al | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of **5** sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. (*sent to the applicant and to the International Bureau*) a total of sheets, as follows:
 - sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

| | | |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Date of submission of the demand 9 August 2004 | Date of completion of the report 30 November 2004 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer STEVEN CHEW Telephone No. (02) 6283 2248 |

Box No. I Basis of the report

With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

- international search (under Rules 12.3 and 23.1 (b))
- publication of the international application (under Rule 12.4)
- international preliminary examination (under Rules 55.2 and/or 55.3)

With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

| | |
|--------|--------------------------------------------------|
| pages | as originally filed/furnished |
| pages* | received by this Authority on with the letter of |
| pages* | received by this Authority on with the letter of |

the claims:

| | |
|--------|-----------------------------------------------------------|
| pages | as originally filed/furnished |
| pages* | as amended (together with any statement) under Article 19 |
| pages* | received by this Authority on with the letter of |
| pages* | received by this Authority on with the letter of |

the drawings:

| | |
|--------|--------------------------------------------------|
| pages | as originally filed/furnished |
| pages* | received by this Authority on with the letter of |
| pages* | received by this Authority on with the letter of |

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to the sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|----------------------------------|-----|
| Novelty (N) | Claims 9-11, 20-22, 31-33, 42-44 | YES |
| | Claims 1-8, 12-19, 23-30, 34-41 | NO |
| Inventive step (IS) | Claims | YES |
| | Claims 1-44 | NO |
| Industrial applicability (IA) | Claims 1-44 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

- D1. CA 1192493
- D2. WO 1986/002267
- D3. EP 0287210
- D4. US 5114957
- D5. US 5658946
- D6. WO 1999/059585
- D7. WO 1999/063816
- D8. US 6225307
- D9. US 6321750
- D10. US 6407131

Novelty (N) claims 1-8, 12-19, 23-30, 34-41

All of the above documents individually disclose citrate and/or succinate salts.

D1 discloses pharmaceutical compositions comprising lithium salts, including lithium citrate or lithium succinate together with lysine (see claim 1, examples 12-15, 17, and 24). The composition is disclosed to be used in the treatment of various conditions including lesions arising from herpes simplex or herpes zoster (see page 6, lines 35-38). Therefore claims 1-8, 12-19, 23-30, and 34-41 lack novelty in light of this citation.

D2 discloses a sulphosuccinate compound, preferably dioctyl Na sulphosuccinate (also known as docusate sodium) for the treatment of herpes simplex-1 or -2 (see examples 9, 10, 16, 19, 20, 27, claims 1, 6, 7, 9, 12, 16, 18, 19, 21.) Therefore claims 1, 4-8, 12, 15-19, 23, 26-30, 34, and 37-41 lack novelty in light of this citation.

D3 discloses pharmaceutical compositions comprising antiviral agent lithium succinate administered alone or in combination with other antiviral agents used in the treatment of herpes simplex (see page 2, line 28 - page 3 line 40, tables 1-12, claims 3 and 4). Therefore claims 1, 4-8, 12, 15-19, 23, 26-30, 34, and 37-41 lack novelty in light of this citation.

D4 discloses tocopherol, in the form of tocopheryl succinate used in the treatment and prophylaxis of herpes (see column 2, lines 43, 62, example II, claims 6 and 17). Therefore claims 1, 4-8, 12, 15-19, 23, 26-30, 34, and 37-41 lack novelty in light of this citation.

Continued in supplemental box

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000018

Box No. VI Certain documents cited

Certain published documents (Rule 70.10)

| Application No. <u>Patent No.</u> | Publication date <u>(day/month/year)</u> | Filing date <u>(day/month/year)</u> | Priority date (valid claim) <u>(day/month/year)</u> |
|--------------------------------------|---------------------------------------------|----------------------------------------|---------------------------------------------------------|
| P, X WO 2003055535 | 10 July 2003 | 20 December 2002 | 21 December 2001 |

This document discloses all the features of claims 1, 4-9, 12, 15-20, 23, 26-31, 34, 37-42.

See page 9, lines 16-20; page 11, lines 9-13; example 1, ATO761; claims 14 and 36.

With regard to the document(s) listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

D5 discloses stannous carboxylates, such as stannous citrate used for the treatment of herpes (see column 2, lines 48-55, column 3, line 35, claim 1). Therefore claims 1, 4-8, 12, 15-19, 23, 26-30, 34, 37-41 lack novelty in light of this citation.

D6 discloses a benzimidazole of formula (1) in the citrate salt form used in the treatment of herpes (see the abstract; page 5, line 29 - page 6, line 3; page 6, lines 11-13, 20-26; claim 4). Therefore claims 1, 4-8, 12, 15-19, 23, 26-30, 34, and 37-41 lack novelty in light of this citation.

D7 discloses a pharmaceutical composition comprising a zinc carboxylate such as zinc citrate together with an amino acid used in the treatment of epidermal irritations and infections such as herpes (see the abstract; page 4, lines 8-10; page 5, lines 10-14; page 7, lines 24-26; claims 1, 9, 10, 21, 26). Therefore claims 1, 4-8, 12, 15-19, 23, 26-30, 34, and 37-41 lack novelty in light of this citation.

D8 discloses a carbamic acid ester of formula (1) in the citrate salt form used in the treatment of herpes (see column 3, lines 53-56; column 4, lines 43-47; column 5, lines 48-49; claims 3, 7 and 11). Therefore claims 1, 4-8, 12, 13, 15-19, 23, 24, 26-30, 34, 35, and 37-41 lack novelty in light of this citation.

D9 discloses zinc salts such as zinc citrate and zinc succinate used in the treatment of herpes (see column 9, lines 9-14 and 48-55; example 11; claims 2 and 3). Therefore claims 1, 4-8, 12, 13, 15-19, 23, 24, 26-30, 34, 35, and 37-41 lack novelty in light of this citation.

D10 discloses benzimidazole compounds of formula (1) in the citrate salt form used in the treatment of herpes (see column 6, lines 13-15, 46-48; claim 10). Therefore claims 1, 4-8, 12, 15-19, 23, 26-30, 34 and 37-41 lack novelty in light of this citation.

Inventive Step (IS) claims 1-44

Claims 1-8, 12-19, 23-30, and 34-41 lack an inventive step for the reasons stated above.

Claims 9-11, 20-22, 31-33 and 42-44 lack an inventive step in the light of D1-D10. The claimed invention differs from the cited art in the use of the specific succinate or citrate salts listed in the claims. However this difference does not require any inventive skill. In addition, there does not appear to be any surprising or unexpected effect for said embodiments.

Industrial Applicability

The invention defined in claims 1-44 is industrially applicable.